

Introduced by Senator Jackson

February 22, 2013

An act to add Section 117647 to, and to add Chapter 12 (commencing with Section 118365) to Part 14 of Division 104 of, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 727, as introduced, Jackson. Medical waste: pharmaceutical product stewardship program.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, including pharmaceutical waste, as defined. Existing law requires, among other things, that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. Under the law, an enforcement agency may bring an action to enjoin the violation or threatened violation of those provisions or issue a specified order to a person who is responsible for a violation or threatened violation. A violation of that order, and other provisions of law, is a crime.

This bill would, effective January 1, 2015, prohibit a producer of a pharmaceutical that is a cover drug, as defined, from selling or distributing that pharmaceutical in the state unless it is included in a product stewardship plan that is approved by the department. This bill would require each producer to operate, individually or jointly with other producers, an approved product stewardship program or to enter into an agreement with a stewardship organization, as defined, to operate that program on the producer's behalf. This bill would require a producer, group of producers, or stewardship organization, if applicable,

to pay all associated costs with its product stewardship program, as specified, including the costs incurred by the state for administration and enforcement of the program. The bill would prohibit the producer from charging specified fees to recover the costs of its program.

This bill would require a producer, individually or jointly with other producers, in consultation with specified entities, to develop a product stewardship plan that includes, among other things, certification that the product stewardship program will accept all unwanted products, except as specified, contact information for the individual or entity submitting the plan and for each producer participating in the program, and a description of the methods by which unwanted products will be collected in the state. This bill would require the producer, group of producers, or stewardship organization operating the program to prepare and submit a written report to the department, as prescribed. This bill would require the department to administer any penalties under those provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 117647 is added to the Health and Safety
- 2 Code, to read:
- 3 117647. (a) "Covered drugs" means all drugs as defined in
- 4 Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA)
- 5 (21 U.S.C. 321(g)(1)), and covered under Section 503 of the act
- 6 (21 U.S.C. Section 353(b)(1)), including both brand name and
- 7 generic drugs.
- 8 (b) Covered drugs do not include any of the following:
- 9 (1) Vitamins or supplements.
- 10 (2) Herbal-based remedies, or homeopathic drugs, products, or
- 11 remedies.
- 12 (3) Cosmetics, soap, with or without germicidal agents, laundry
- 13 detergent, bleach, household cleaning products, shampoo,

1 sunscreen, toothpaste, lip balm, antiperspirants, or other personal
2 care products that are regulated as both cosmetics and
3 nonprescription drugs under the FFDCA.

4 (4) Drugs for which a producer provides a take-back program
5 as part of an FFDCA managed risk evaluation and mitigation
6 strategy.

7 (5) Drugs that are biological products, as defined in Section
8 262(i) of Title 42 of the United States Code, if the producer already
9 provides a take-back program

10 (6) Pet pesticide products contained in pet collars, powders,
11 shampoos, topical applications, or other delivery systems.

12 (7) Nonprescription drugs.

13 SEC. 2. Chapter 12 (commencing with Section 118365) is
14 added to Part 14 of Division 104 of the Health and Safety Code,
15 to read:

16
17 CHAPTER 12. PHARMACEUTICAL PRODUCT STEWARDSHIP
18 PROGRAM
19

20 118365. For purposes of this chapter, “stewardship
21 organization” means a nonprofit organization created by a producer
22 to implement the pharmaceutical product stewardship program
23 described in Section 118365.1.

24 118365.1. (a) Effective January 1, 2015, a producer of a
25 pharmaceutical that is a covered drug shall not sell or distribute
26 that pharmaceutical in the state unless it is included in a product
27 stewardship plan approved by the department.

28 (b) Each producer shall do one of the following:

29 (1) Operate, individually or jointly with other producers, a
30 product stewardship program approved by the department.

31 (2) Enter into an agreement with a stewardship organization to
32 operate, on the producer’s behalf, a product stewardship program
33 approved by the department.

34 (c) (1) A producer, group of producers, or stewardship
35 organization shall pay all administrative and operational fees
36 associated with its product stewardship program, including the
37 costs of collecting, transporting, and disposing of unwanted
38 products collected from residential generators and the recycling
39 or disposal, or both, of packaging collected with the unwanted
40 product.

(2) A producer, group of producers, or stewardship organization shall pay for all fees associated with obtaining compliance with the California Environmental Quality Act (Division 13 (commencing with Section 21000) of the Public Resources Code), if required, for a product stewardship program and product stewardship plan.

(3) A person or producer shall not charge a specific point-of-sale fee to a consumer to recover the costs of its product stewardship program, and shall not charge a specific point-of-collection fee at the time the unwanted products are collected from residential generators or delivered for disposal.

(4) A producer, group of producers, or stewardship organization shall pay all costs incurred by the state, including, but not limited to, the department's costs, for the administration and enforcement of its pharmaceutical product stewardship program. Exclusive of any fines, the state shall only recover the actual costs of administration and enforcement under this chapter, and shall not charge any amounts under this chapter in excess of the actual administrative and enforcement costs.

118365.2. In consultation with local governments, water districts, sanitation districts, pharmacies, waste haulers, environmental health officers, and all interested stakeholders, the producers, individually or jointly with other producers, shall develop a product stewardship plan.

(a) Each product stewardship plan required under Section 118365.1 shall contain all of the following:

(1) Certification that the product stewardship program will accept all unwanted products, regardless of who produced them under a joint plan, unless excused from this requirement by the department as part of its approval of the plan.

(2) Contact information for the individual and the entity submitting the plan and for each of the producers participating in the product stewardship program.

(3) A description of the methods by which unwanted products from residential generators will be collected in the state and an explanation of how the collection system will be convenient and adequate to serve the needs of all California residents.

(4) A description of how the product stewardship plan will provide collection services for unwanted products in all areas of

1 California that are convenient to the public and adequate to meet
2 the needs of the population in the area being served.

3 (5) If applicable, the location of each collection site and
4 locations where envelopes for a mail-back program are available.

5 (6) A list containing the name, location, permit status, and record
6 of any penalties, violations, or regulatory orders received in the
7 previous five years by each person that will be involved in
8 transporting unwanted products and each medical waste or
9 hazardous disposal facility proposed to participate in the product
10 stewardship program.

11 (7) A description of how the unwanted products will be safely
12 and securely tracked and handled from collection through final
13 disposal, and the policies and procedures to be followed to ensure
14 security and adherence to highest management standards.

15 (8) A description of public education and outreach activities
16 that are consistent with this chapter, and how the effectiveness of
17 those programs and activities will be evaluated.

18 (9) A description of how the scope and extent of the product
19 stewardship program is reasonably related to the amount of covered
20 drugs that are sold in the state by the producer, or group of
21 producers.

22 (10) A starting date for the collection of unwanted products.

23 (11) If applicable, a description of how support will be provided
24 to any law enforcement agencies within the state that operate, or
25 later agree to operate, a collection program for controlled
26 substances, including the provision of a collection kiosk with
27 appropriate accessories and signage, the ability to accept controlled
28 substances and other covered drugs, and technical support, up to
29 and including an appropriate person to provide on-site assistance
30 with the sorting and separation of controlled substances at no cost
31 to a participating law enforcement agency. Otherwise, controlled
32 substances are expressly excluded from this chapter,
33 notwithstanding any other provision.

34 (12) A description of how collection sites for unwanted products
35 may be placed at appropriate retail stores in the state, including a
36 description of the involvement of the retail store. Retailers are not
37 required or mandated to host collection sites, and nothing in this
38 chapter shall be interpreted as requiring that participation.

39 (13) If more than one producer will be involved in a proposed
40 product stewardship program, the plan for that program shall

1 include a fair and reasonable manner for allocating the costs of
2 the program among the participants in that program, so that the
3 portion of costs paid by each producer is reasonably related to the
4 amount of covered drugs that producer sells in the state.

5 118365.3. On or before January 1, 2016, or at a later date as
6 approved in writing by the department, and in each subsequent
7 year, each producer, group of producers, or stewardship
8 organization operating a product stewardship program shall prepare
9 and submit to the department an annual written report describing
10 the program's activities during the previous reporting period.

11 118365.4. The department shall administer the penalty
12 provisions for this chapter.

13 SEC. 3. No reimbursement is required by this act pursuant to
14 Section 6 of Article XIII B of the California Constitution because
15 the only costs that may be incurred by a local agency or school
16 district will be incurred because this act creates a new crime or
17 infraction, eliminates a crime or infraction, or changes the penalty
18 for a crime or infraction, within the meaning of Section 17556 of
19 the Government Code, or changes the definition of a crime within
20 the meaning of Section 6 of Article XIII B of the California
21 Constitution.